EXHIBIT 31

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, vs. MYLAN PHARMACEUTICALS, INC., Defendant.	)	Civil Action No. 3:11-CV-02506-JAP-DEA

DEPOSITION OF DR. RUSSELL MUMPER
New York, New York
June 6, 2012

Reported By:
CATHI IRISH, RPR, CLVS, CCR

June 6, 2012
9:30 a.m.

Deposition of DR. RUSSELL MUMPER, held at the offices of Alston & Bird, 90 Park Avenue, New York, New York, before Cathi Irish, a Registered Professional Reporter and Notary Public of the State of New York.

A P P E A R A N C E S:

HOGAN LOVELLS US LLP
Attorneys for Plaintiffs
875 Third Avenue
New York, New York 10022
BY: ARLENE L. CHOW, ESQ.
TAKASHI OKUDA, ESQ.

ALSTON & BIRD LLP
Attorneys for Defendant
90 Park Avenue
New York, New York 10016
BY: DEEPRO R. MUKERJEE, ESQ.

D R. R U S S E L L M U M P E R, called as a witness, having been duly sworn by a Notary Public, was examined and testified as follows:

EXAMINATION

BY MS. CHOW:

Q. Good morning.
A. Good morning.
Q. How many times have you been deposed?
A. One time previously.
Q. Was that in the context of a patent litigation?
A. It was.
Q. How many times have you prepared an expert report?
A. I prepared two for the Watson Cephalon trial and so those are expert reports, and I obviously prepared the declaration for this trial.
Q. Okay. For the Watson case, did you prepare an expert report in relation to claim construction?
A. No.
Q. Just generally, was it in relation to infringement, validity?

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A. It was -- the first one was infringement. Second one was validity.
Q. And did that case involve an orally disintegrating tablet?
A. It did.
Q. Did that case go to trial?
A. It did.
Q. What was the product at issue?
A. This was Cima and Cephalon, two companies. This was their Fentora product, buccal effervescent fentanyl.
Q. So that product was a buccal effervescent ODT; is that correct?
MR. MUKERJEE: Objection.
MS. CHOW: You may answer.
MR. MUKERJEE: You may answer.
THE WITNESS: Yes.

BY MS. CHOW:

Q. Where did that ODT disintegrate?
A. In the buccal cavity.
Q. What do you mean by in the buccal cavity?
A. That the Fentora product was meant to be inserted into the mouth, placed against the

cheek, the buccal tissue, and disintegrate at that point.

Q. Now, that product was an ODT so that was an orally disintegrating tablet; is that correct?

MR. MUKERJEE: Objection.

THE WITNESS: That is correct.

BY MS. CHOW:

Q. Could that product be administered outside of the mouth?

A. Can you clarify by what you mean administered outside of the mouth.

Q. I understand. Were there different forms of administration for that product?

A. The prescribing information had explicit instructions that the tablet was to be placed in the mouth against the buccal tissue at which time it would disintegrate, produce effervescence and the claim was that effervescence would promote absorption of the active fentanyl.

Q. Was that product disintegrated outside of the mouth in water prior to administration to the patient?

MR. MUKERJEE: Objection, form.

THE WITNESS: I don't know if it was. I do know. I recall from the prescribing information that it was very clear that it was to be placed in the mouth. Now, did patients -- or doctors instruct their patients to predissolve it in water? They may have. I have no knowledge of that.

BY MS. CHOW:

Q. For your infringement report, did you opine on claim construction of the patent?

MR. MUKERJEE: Objection, asked and answered.

THE WITNESS: No, claim -- there was an agreement before I was to write my expert reports about claim construction, so I didn't write a report specifically about claim construction. There may have been in my noninfringement report my opinions about what certain terms meant.

BY MS. CHOW:

Q. Okay. Are you saying that there was a claim construction in place prior to your opining on infringement; is that what you're saying?

A. As I recall, the judge was deferring

claim construction judgment and was including that in the noninfringement and validity contentions to be decided at trial, is my best understanding.

Q. What law firm did you work with in that case?

A. Frommer Lawrence & Haug.

MS. CHOW: I'm going to mark as Mumper Exhibit 1 U.S. patent 6,328,994.

(Mumper Exhibit 1, U.S. patent 6,328,994, marked for identification.)

BY MS. CHOW:

Q. Do you recognize this document?

A. Yes.

Q. Is it the patent-in-suit or one of the patents-in-suit at issue in this case?

A. Yes.

Q. I'd like to direct your attention to claim 1. It's in column 37.

As you can see, claim 1 includes a sustained-release agent. Do you see that?

MR. MUKERJEE: Objection.

THE WITNESS: I see sustained-release agent listed in claim 1.

BY MS. CHOW:

Q. Okay. What is the purpose of the sustained-release agent in claim 1 of the '994 patent?

MR. MUKERJEE: Objection.

THE WITNESS: As I understand the purpose of the sustained-release agent as written in the '994 patent is the traditional meaning of a sustained-release agent as known by people skilled in the art on what a sustained-release agent would do to prolong or sustain drug release based on producing diffusional barrier to control the rate of drug release and defusion through that barrier over time. Ultimately to sustain blood levels over a period of time.

BY MS. CHOW:

Q. Is it your position that the orally disintegrable tablet described in claim 1 of the '994 patent is a sustained-release product?

MR. MUKERJEE: Objection.

THE WITNESS: That's not my position. My position is that the tablet described in claim 1 contains a sustained-release agent.

BY MS. CHOW:

Q. So is it your position that the tablet contains a sustained-release agent but it does not have sustained-release functionality?

MR. MUKERJEE: Objection.

THE WITNESS: I have no knowledge on whether the tablet described in claim 1 has sustained-release properties. My position is the tablet in claim 1 contains a sustained-release agent that was well known at the time of filing to provide certain functions and those were described in my declaration.

BY MS. CHOW:

Q. So it is your understanding that the tablet described in claim 1 of the '994 patent does not necessarily have sustained-release properties?

MR. MUKERJEE: Objection, mischaracterizes his testimony.

THE WITNESS: My position is that the tablet that's described in claim 1 may not necessarily be a sustained-release tablet but that it contains a sustained-release agent by

definition.

BY MS. CHOW:

Q. So why is a sustained-release agent included in the tablet described by claim 1 of the '994 patent?

MR. MUKERJEE: Objection.

THE WITNESS: So in my reading of the '994 patent, it is silent as to the purpose of the inclusion of a sustained-release agent in the tablet that's described in claim 1. In the specifications that mention the term sustained-release agent, that has well-known meaning in the field to people of ordinary skill. And so I look at the sustained-release agent, its well-known function to control or sustain drug release, and I would conclude that it was -- I would conclude that it was included in the tablet to impart those types of properties.

BY MS. CHOW:

Q. So is it your position that you can surmise what the purpose of the sustained-release agent is in the tablet described by claim 1 of the '994 patent based on your understanding of one of

skill in the art but not based on what is taught in the specification?

MR. MUKERJEE: Objection.

THE WITNESS: Can you repeat that question, please?

BY MS. CHOW:

Q. So is it your position that you can surmise what the purpose of the sustained-release agent is in the tablet described by claim 1 of the '994 patent based on your understanding of one of skill in the art but not based on what is taught in the specification?

MR. MUKERJEE: Same objection.

THE WITNESS: So my position is that the '994 patent, the specifications talk about a sustained-release agent but they don't teach explicitly and literally the function of the sustained-release agent. So as I read that, I understand what a sustained-release agent is and what its purpose is and I conclude that that was the purpose of the sustained-release agent in claim 1.

I understand in looking at the prosecution history, the Shimizu declaration

and the Byrn declaration, that they are alleging that the sustained-release agent has a different function as I conclude that the sustained-release agent would have after reading the '994 patent.

BY MS. CHOW:

Q. Let's go to the patent, column 19, lines 9 through 31.

Are you there?

A. Column 19, lines 9 through 31.

Q. Actually it's probably more -- sorry, starting at line 25. So it's more 25 to 31. It's a portion of the specification described as acid resistance, okay? Do you see the acid resistance test?

A. I do.

Q. What is the purpose of the acid-resistance test in the '994 patent as set forth under column 19?

MR. MUKERJEE: Objection. Dr. Mumper can take as much time as he needs.

BY MS. CHOW:

Q. Dr. Mumper, is this the first time you've considered this question, what is the

purpose of the acid-resistance test in the '994 patent?

MR. MUKERJEE: Objection.

THE WITNESS: No.

BY MS. CHOW:

Q. So my question --

A. Can you repeat the first question?

(Record read.)

MR. MUKERJEE: Same objection.

THE WITNESS: In my opinion, the purpose of the acid-resistance test is to verify the integrity of the enteric coating on the granule and my opinion is consistent with what is taught in the '994 patent. I'm looking for that particular paragraph and I have not been able to identify it on this document.

BY MS. CHOW:

Q. In the '994 patent, what helps protect the integrity of the enteric coat of the orally disintegrating tablet?

MR. MUKERJEE: Objection.

THE WITNESS: You said orally disintegrating tablet?

BY MS. CHOW:

Q. In the tablet taught by the '994 patent, what helps protect the integrity of the enteric coat?

MR. MUKERJEE: Objection.

THE WITNESS: So the '994 patent teaches an orally disintegrable tablet which in my opinion is different. What protects the integrity of the enteric coating is the fact that the enteric coating agent has specific physical chemical properties and when it is coated on the granules is insoluble and will not dissolve at low pH of the stomach, will dissolve at higher pHs as the acidic moieties become ionized.

BY MS. CHOW:

Q. Does the sustained-release agent help protect the integrity of the enteric coat in the tablet taught by the '994 patent?

A. I have no specific knowledge on whether the sustained-release agent helps protect the integrity of the enteric coating on top of the granules. I know that in the Shimizu declaration, it was claimed and concluded by Shimizu that it

does.

Q. In preparing your report, did you investigate the physical properties of known sustained-release agents?

MR. MUKERJEE: Objection.

THE WITNESS: In preparing my report, and specifically to help develop my opinion on the term sustained-release agent, I did do -- I relied on references that are in my declaration as well as my own knowledge of what a sustained-release agent function is in an orally -- in oral tablets.

BY MS. CHOW:

Q. Do you have any understanding as to whether or not known sustained-release agents can be used to cushion enteric coats?

A. Can you repeat the question?

Q. Do you have any understanding as to whether or not known sustained-release agents can help protect the integrity of enteric coats on tablets?

A. I'd like you to repeat the question because I think you asked two different forms that have two different meanings to me of what a

sustained-release agent would be doing.

Q. Do you have any understanding as to whether or not known sustained-release agents can help protect the integrity of the enteric coat?

A. I have knowledge of agents that have been included in enteric coatings that are intended to be added during the enteric coating process. These agents may have other functions in the -- in dosage forms such as sustained-release.

Q. You're not answering my question. The question was very specifically tailored to protecting the integrity of the enteric coat. I'm using your own words, okay, so do you have any understanding whether or not sustained-release agents can help protect the integrity of the enteric coat?

MR. MUKERJEE: Objection, asked and answered.

THE WITNESS: I think I am answering the question. Excipients in dosage forms, if you look at the Handbook of Pharmaceutical Excipients, Merck Index, they can have many different functions and what I said was that agents can be -- I'm aware of agents being

Application Publication 2009/0304789, marked for identification.)

BY MS. CHOW:

Q. I'm just going to direct your attention to paragraphs 84 and 86 which is on page 5.

A. Can you tell me again the paragraphs you would like me to look at?

Q. Paragraph 84 and then paragraph 86, and just so you know where I'm going, paragraph 86 mentions Eudragit L30D-55 so that's --

A. I've read paragraphs 84 and 86.

Q. Does U.S. 2009/0304789 teach that Eudragit L30D-55 can be used as a sustained-release agent?

MR. MUKERJEE: Objection. Again, Dr. Mumper, if you need to read any other portions for context, feel free to do so.

THE WITNESS: I would have to read the whole -- this is the first time I've seen this patent application publication, so I would have to read the whole thing to understand what they are teaching.

BY MS. CHOW:

Q. Based on what you've read so far, is

this patent application associating Eudragit L30D-55 with sustained-release functionality?

MR. MUKERJEE: Objection. Again, if you need to read other portions for context, feel free to do so.

THE WITNESS: I don't know what it's associating until I read the whole patent.

BY MS. CHOW:

Q. Is it possible for a specific Eudragit to be used as both a sustained-release agent and an enteric coating agent?

A. I think the answer to that question is related to my clarification request before, as in what context? In the context of coating a drug-coated inert core where you have an enteric coating and that enteric coating of a Eudragit must have well-known properties to be an enteric coating, or is it in general, any Eudragit available in any context in any dosage form, whether it be a granule, a tablet, a gel, anything. Can it be used as both? Is that what you're asking, the latter?

Q. I'm asking you as one of skill in the art, is it your understanding that a specific

Eudragit can be used as both a sustained-release agent and an enteric coating agent? Is that possible?

MR. MUKERJEE: Objection.

THE WITNESS: I think that question needs context for me. Again, if it's an oral dosage form and you have a coated tablet or coated granules and you want to impart acid resistance to its context, you need certain properties of that Eudragit.

Specifically as it relates to '994, if you wanted to impart an enteric coating to granules to provide acid resistance, that coating of the appropriate enteric coating agent would not be a sustained-release agent. So I think to answer your question in the most general way, I would need to take a specific dosage form understanding what functions you wanted to have of that dosage form to answer that question.

BY MS. CHOW:

Q. Now, you previously testified that you reviewed the Shimizu declaration that was submitted during the prosecution of the '994

patent in relation to the acid-resistance test; is that right?

A. I reviewed the Shimizu declaration.

Q. Is it your understanding that Dr. Shimizu represented that the sustained-release agent was used in the '994 to help protect the integrity of the enteric coat?

MR. MUKERJEE: Objection.

THE WITNESS: As I recall from the declaration of Dr. Shimizu, that he utilized the example 9 in the '994 patent and compared that to a prior art formulation and concluded in the declaration or tested the two formulations, one from example '994 and one from the prior art and looked at acid-resistance, and from that acid-resistance data made the conclusion that the example 9 in the '994 patent provided greater acid-resistance which he attributed to the ability of the sustained-release agent to cushion or provide protection to the enteric coating layer.

BY MS. CHOW:

Q. So it's your understanding that the

inventor told the PTO during the prosecution of the '994 patent that the sustained-release agent provided protection to the enteric coating layer; is that correct?

MR. MUKERJEE: Objection. Maybe, Arlene, you want to put the declaration in front of the witness.

THE WITNESS: Can I have the declaration to review?

MS. CHOW: Sure. I was just restating your testimony. I was repeating it.

Let's mark as Mumper 4 a declaration by Toshihiro Shimizu dated December 18, 2000.

(Mumper Exhibit 4, declaration by Toshihiro Shimizu, marked for identification.)

THE WITNESS: My recollection as I just stated is consistent with Shimizu's conclusion in the -- in his declaration that the example B from example 9 in '994 had suitable strength and was not damaged through production and had superior acid-resistance, and he concluded that the coating layer of fine granules of the present invention are not damaged after compression or shock and further has superior

acid resistance. His conclusion is consistent with my recollection as I just described.

BY MS. CHOW:

Q. And he concluded that the sustained-release agent was responsible for the superior acid-resistance, correct?

A. He did not explicitly state that in the conclusion. What he explicitly stated was that the coating layer is not damaged and has superior acid-resistance. His conclusion did not explicitly state that it was because of the sustained-release agent.

Q. But you derive that from his declaration?

MR. MUKERJEE: Objection.

THE WITNESS: I'm acknowledging what he's concluding as his conclusion. He didn't conclude specifically and literally that the sustained-release agent was responsible for providing that superior acid-resistance. In comparing example A to example B, those were different formulations with different ingredients and so...

BY MS. CHOW:

Q. Is it your position that this Shimizu declaration, which is Mumper 4, has no bearing on the claim construction for, in quotes, "an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent"?

MR. MUKERJEE: Objection, form.

THE WITNESS: You asked if that's my position or -- that's not my position.

BY MS. CHOW:

Q. So it's your position that Mumper 4, which is the Shimizu declaration, has bearing on the claim construction for, in quotes, "an enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent"?

A. I believe that the Shimizu declaration is very important for -- and I used it and relied upon it to determine claim construction as it relates to the '994 patent.

Q. Now, let's look at the patent again. I'm just going to grab an example. Let's just take example 1, okay?

A. I'm sorry, this is the '994?

Q. Yes, Mumper 1.

A. Okay.

Q. Now, example 1 includes Eudragit NE30D and enteric coat. Do you see that? That's in column 20 of the '994 patent.

A. In column 20, line 32 or so I see Eudragit NE30D.

Q. In example 1, is the Eudragit NE30D used to release the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time?

A. I'm sorry, you said L30D-55.

Q. No. Oh, you're reading into my question but no. Example 1. That's funny.

Is the Eudragit NE30D used to release the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time?

A. So NE30D and why it's used in example 1?

Q. Yes, that's correct?

A. Or its function in example 1.

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My opinion is that Eudragit NE30D in example 1 is used as -- or is a sustained-release agent that's present at a defined ratio relative to the enteric coating agent and is added at the same time as the enteric coating agent to impart the function as a sustained-release agent.

MR. MUKERJEE: Arlene, it's 11 o'clock. As I indicated, I need five minutes.

MS. CHOW: Why don't we make it a 10-minute break.

MR. MUKERJEE: That's fine.

(Recess taken from 11:00 a.m. to 11:13 a.m.)

BY MS. CHOW:

Q. You didn't answer my question actually before the break so I'm going to ask it again.

Example 1 of the '994 patent, is Eudragit NE30D used to release the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time?

A. I don't have any knowledge of how Eudragit NE30D functions in this specific example. I will say that Eudragit NE30D is taught by the

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inventors to be a sustained-release agent and as a matter of function, sustained-release agents are known to prolong or control the rate of drug release.

Q. Would your answer be the same for example 2, example 3, example 4, example 5, example 6, example 7, example 8, and example 9 of the '994 patent?

MR. MUKERJEE: Objection. Dr. Mumper, take as much time as you need to go through each of these examples.

THE WITNESS: And you're asking specifically about the Eudragit NE30D?

BY MS. CHOW:

Q. I'll restate the question. In examples 2 -- so this is the question.

In examples 1 through 9 of the '994 patent, is the Eudragit NE30D being used to release the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time?

THE WITNESS: I would like the reporter to, if you could read back my answer to the previous question. I think that's what you're

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asking me.

(The following was read by the reporter: "ANSWER: I don't have any knowledge of how Eudragit NE30D functions in this specific example. I will say that Eudragit NE30D is taught by the inventors to be a sustained-release agent and as a matter of function, sustained-release agents are known to prolong or control the rate of drug release.")

THE WITNESS: So my answer, my previous answer would be the same as you asked for examples 2 through 9.

BY MS. CHOW:

Q. So you don't have any knowledge of how Eudragit NE30D is functioning in examples 1 through 9 of the '994 patent, yes?

MR. MUKERJEE: Objection.

THE WITNESS: I don't have knowledge as to how Eudragit NE30D is functioning in the tablets in examples 1 through 9.

BY MS. CHOW:

Q. Okay. Similar question.

In claim 1 of the '994 patent, is the

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sustained-release agent used to release the active ingredient at a predetermined rate in order to maintain a constant or prolonged drug concentration for a specific period of time?

A. I don't have any knowledge of whether the sustained-release agent listed in claim 1 is causing the drug in the tablets to be released in a prolonged or sustained manner.

Q. Is it your understanding that claim 1 is not limited to examples 1 through 9 of the '994 patent?

MR. MUKERJEE: Objection, calls for a legal conclusion.

THE WITNESS: Can you restate the question?

BY MS. CHOW:

Q. Is claim 1 of the '994 patent limited to just the examples 1 through 9?

MR. MUKERJEE: Same objection, calls for a legal conclusion.

THE WITNESS: Would you like me to answer?

BY MS. CHOW:

Q. Absolutely.

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A. My understanding is consistent with the statement in '994 that the examples are illustrative but by no means limit the present invention.

Q. Now, I'd like to direct your attention to column 16, lines 37 through -- you know what, it's roughly around line 40. The patent states the coating layer may be constructed by plural layers.

Do you see that?

A. I see that.

Q. Is it your understanding that the enteric coating layer of claim 1 can be constructed by plural layers?

MR. MUKERJEE: Objection.

THE WITNESS: My understanding from column 16, line 37, is that the enteric coating layer, there may be more than one. There could be two, there could be three, but that each enteric coating layer must contain both an enteric coating agent and a sustained-release agent together in each layer.

MS. CHOW: Let me mark as Exhibit

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Mumper 5 the joint claim construction statement that was entered into in this case by the parties.

(Mumper Exhibit 5, joint claim construction statement, marked for identification.)

BY MS. CHOW:

Q. And I'll direct your attention to page 11 just to cut to the chase. Have you seen that document before?

A. I believe I've seen this document before.

Q. All right. Now, you see there that plaintiffs have a construction for enteric coating layer on top of page 11; do you see that? I'm going to read it into the record.

So plaintiffs' construction for enteric coating layer is the enteric coating layer may be constructed by plural (e.g. 2 or 3) layers.

Do you see that?

A. I see the enteric coating layer may be constructed by plural (e.g. 2 or 3) layers.

Q. Is there anything wrong with that construction?

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MR. MUKERJEE: Objection.

THE WITNESS: What do you mean by wrong?

BY MS. CHOW:

Q. Do you disagree with it? Basically I don't know if you agree or disagree with it so I want to know, do you agree or disagree?

A. I think that that statement, the enteric coating layer may be constructed by plural (e.g. 2 or 3) layers is verbatim from column 16, line 37 and 38, and so it's consistent with '994.

Q. Okay. So you don't disagree with it, correct?

Maybe you didn't hear it. Strike that question.

A. I was just carefully thinking of my answer.

Q. Oh, you are? Because I couldn't tell whether you heard or not.

A. You're asking if I disagree or agree with that statement?

Q. You're saying it's consistent with the patent?

A. It's consistent with the patent.

MUMPER

Q. That's fine.

Let's turn to page -- I think it's up one, page 8 of Mumper 5, okay?

Now, this is the construction for enteric coating layer comprising a first component which is an enteric coating agent and a second component which is a sustained-release agent.

Now, you see plaintiffs' construction right there?

A. Yes.

Q. It's my understanding that you disagree with plaintiffs' construction for this claim term; is that correct?

A. Yes.

Q. Is there anything fundamentally wrong with plaintiffs' construction?

MR. MUKERJEE: Objection.

BY MS. CHOW:

Q. So it's one thing if you disagree with it but I'm asking you if there's anything wrong with it.

MR. MUKERJEE: Objection.

THE WITNESS: I'd like you to clarify the word "wrong" and what do you mean by

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any kind?

MR. MUKERJEE: Objection.

THE WITNESS: When -- when measuring granule size of a powder, you typically have a span of particles and an average and so you would report the data as an average plus a standard deviation with respect to the span or the breadth of that particle size population. That's different than the error that might be associated with measuring the average particle size and the span of that granule population.

BY MS. CHOW:

Q. Are you familiar with the USP or the U.S. Pharmacopeia?

A. I am familiar with the USP.

Q. What is it?

A. It is a compendium of industry-accepted guidelines on various aspects related to raw materials, drugs and the testing of those.

Q. Does the USP set forth the standards for persons of skill in the art of pharmaceutical sciences?

MR. MUKERJEE: Objection, form.

THE WITNESS: Can you repeat the

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question?

BY MS. CHOW:

Q. Does the USP set forth standards for persons of skill in the pharmaceutical arts?

A. In my opinion, the USP sets forth a series of guidelines to guide the industry on acceptable specifications and methods to test raw materials, ingredients and drugs.

Q. Does the USP set forth a series of guidelines to guide the pharmaceutical industry on acceptable specifications and methods in relation to average particle size measurements?

MR. MUKERJEE: Objection.

THE WITNESS: That question is a general question to me because what the USP does is it has guidelines on the testing of powders and particle sizes of those powders based on a specific measure -- method of measurement, so there's not a specification for general measurement because each method that's used to measure particle size is dependent on the method being used, the instrument, and all of the parameters associated with the use of that instrument to

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measure, in this case, average particle diameter.

BY MS. CHOW:

Q. Do persons of skill in the art turn to the USP for guidelines in relation to average particle size measurements?

A. In my opinion, people of ordinary skill in the art turn to the USP as a potential source of guidelines to understand industry -- kind of basic minimum industry standards of how one might do that but that in my experience, an assay that might be developed to determine average particle size in a laboratory for research or product purposes, those assays might be more rigorous than the guidelines set out in the USP.

What the USP intends to do is kind of bring all of the workers in the industry kind of on the same page, per se, as to an accepted practice but it's a minimum standard. It's not a gold standard in my opinion.

Q. So the USP sets forth a minimum standard for the pharmaceutical industry but not necessarily the gold standard; is that your testimony?

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A. My testimony is that in my opinion that the USP sets forward a minimum standard for the testing of various ingredients or products but it doesn't -- it doesn't articulate -- I said gold standard. What I mean is the most rigorous processes that one would employ for the purposes of testing drugs and products for publication or for registration of those products.

(Mumper Exhibit 6, U.S. Pharmacopeia Chapter 429, marked for identification.)

MS. CHOW: I've marked as Mumper 6 U.S. Pharmacopeia Chapter 429 entitled Light Diffraction Measurement of Particle Size.

MR. MUKERJEE: Arlene, for the record, it's a copy of the December 1, 2009 to September 30, 2010 USP; is that correct?

MS. CHOW: I'll take your representation.

MR. MUKERJEE: I'm just reading from the top of the document you've marked as Mumper 6.

MS. CHOW: Okay. The document says what it says.

MUMPER

particle diameter in '994 could be measured by a number of assays to measure average particle diameter, including laser diffraction, and the HEROS RODOS is just one of the laser diffractometers that could be used in that class.

BY MS. CHOW:

Q. Do you agree that USP 429 sets forth a standard of error for measurement of average particle size?

A. Can you repeat the question or can you read it back to me?

(Record read.)

THE WITNESS: The question, I just want to be clear, it's general because this specifically is talking about light diffraction. So your question is specifically related to light diffraction and whether or not it sets forth an accepted standard of error using laser diffraction to measure particle size.

BY MS. CHOW:

Q. Okay.

A. Is that your question?

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Q. My question was: Do you agree that USP 429 sets forth a standard of error for measurement of average particle size?

A. I am having problems with the question because 429 talks about accepted -- accepted fluxes or deviations around measurements that are specific to why that measurement was done. So replicates, system suitability, and so it lays it out. So your question is -- and I should add accuracy and repeatability.

So your question is very general because 429 speaks to accepted fluxes in those data for those different tests of which laser light diffraction will help you to determine.

Q. Would one of skill in the art understand that the average particle size measurement required by claim 1 of the '994 patent would include fluxes or deviations around those measurements?

A. My opinion of claim 1 is that the inventors claimed exactly what is stated here, that fine granules having an average particle diameter of 400 microns or less means that those fine granules had an average particle diameter of

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400 microns or less.

Now, there could be a flux around that average based on the true distribution of the particles but that the average particle diameter was precisely 400 microns or less.

Q. What do you mean when you say there could be a flux around that average based on the true distribution of the particles? I guess I'm not understanding. I mean it's your position that the average -- there's basically a hard cutoff of 400 microns for the average particle diameter; is that your testimony?

A. My testimony is that you have a true average particle diameter of granules and so the average is the 50 percent volume median diameter as defined by '994, I accept that, and there will be a true distribution of those particles. They are not all, let's say, 390 or 300. There's a flux of the true distribution of those particles.

They could be -- let's say it was 330, they could be a range from 310 to 350 but the average in that example is 330. That's what I mean by the flux around the true average particle diameter. It's a different question then to say

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what is the error associated with the measurement of those particles.

My position then is with respect to claim 1 is that the inventors stated what they literally meant, the average particle diameter of those fine granules is 400 microns or less. The single 50 percent weighted volume parameter is always 400 microns or less.

Q. So if I had a tablet that had an average particle diameter of 405 microns, let's say, is it your position it would fall outside claim 1?

A. It would literally fall outside of claim 1, in my opinion.

Q. If I had a tablet that had an average particle diameter of 401 microns, is it your position it would fall outside claim 1?

A. If the average particle diameter was 401, it would literally fall out of claim 1 in '994.

Q. Is it your understanding that average particle diameter and maximum particle diameter are two distinct concepts?

A. My understanding is that average

particle diameter and maximum particle diameter are two different concepts, two different things.

Q. Now, I want you to look at the patent, '994 patent. I want you to compare claim 1 and claim 7.

Do you see that claim 7 captures the concept of a maximum particle diameter of 425 microns or less?

MR. MUKERJEE: Objection as to form. You can answer.

THE WITNESS: I believe that claim 7 says -- is referring to the particle diameter of the fine granules as practically 425 or less and that what I believe they are referring to is the maximum particle diameter.

BY MS. CHOW:

Q. Now, your proposed claim construction for average particle diameter incorporates maximum particle diameter; is that correct? You can look at the joint claim construction chart for reference if you want. It's on page 13.

A. Thank you.

Yes, that is correct, my proposed claim construction incorporates the maximum particle

diameter with the average particle diameter, so wherein the particle diameter of the fine granules is 3- to 400 microns or less with a maximum particle diameter of 425 or less.

Q. And there's also --

A. There's another one.

Q. There's also an earlier -- it's page 2.

So your construction for fine granules having an average particle diameter of 400 microns or less incorporates maximum particle diameter; is that right?

A. Yes, my proposed claim construction states fine granules having an average particle diameter of 400 microns or less with a maximum particle diameter of 425 microns or less. So both of those are incorporated into the claim construction.

Q. So your claim construction for really claim 1 of the patent incorporates a concept that's already set forth in claim 7; is that right?

MR. MUKERJEE: Objection.

THE WITNESS: I'm not sure I understand the question. Can you restate it?

BY MS. CHOW:

Q. Claim 7 describes maximum particle diameter; is that right? Okay, yes, no?

A. Yes, that's true.

Q. When you provided the claim construction for fine granules having an average particle diameter of 400 microns or less for claim 1, did you take claim 7 into account?

A. I did take claim 7 into account. When I constructed the claims, I looked at the term for average particle diameter and I construed it from the teaching of the '994 patent that the maximum particle diameter was inherent in the teachings of '994 with respect to the average particle diameter of 400 micron or less in claim 1, and then I concluded from that that claim 7 was superfluous. It was not necessary, that inherent in claim 1 was the concept of a maximum particle diameter as taught by '994.

Q. Okay. So it's your position that claim 7 was superfluous and not necessary in light of claim 1, correct?

A. My opinion was claim 7 was not necessary in light of my proposed claim

construction for claim 1.

Q. Okay.

Are you familiar with the Journal for Pharmaceutical Sciences?

A. Journal of Pharmaceutical Sciences? I'm familiar --

Q. I will defer to you on that.

A. I am familiar with the Journal of Pharmaceutical Sciences.

Q. Is it peer reviewed?

A. Journal of Pharmaceutical Sciences is peer reviewed.

Q. Have you published in it?

A. I have published in the Journal of Pharmaceutical Sciences.

Q. Is it respected?

A. What do you mean by respected?

Q. Do persons of skill in the art rely on -- strike that.

Are you familiar with the PQRI or the Product Quality Research Institute?

A. I have heard of the institute and am familiar with the basics of what they do.

(Mumper Exhibit 7, article from the

thing, right?
A. Non-effervescent excipients and free of organic acids do not mean the same thing to me.
Q. Now, you understand that the claim originally included the phrase "free of organic acids" but that was subsequently dropped by the patentee, right?
A. My understanding from the prosecution history is that the inventors requested reexamination of the patent based on the discovery of 70 to 72 patents that had not previously been disclosed. And in that analysis, they proposed a reconstruction of their claim that included the term "non-effervescent excipients free of organic acids," and as I recall, the examiner looked at that proposed claim amendment and concluded that there was not sufficient evidence of the term "free of organic acids" in the '632 specifications and struck that.
MS. CHOW: I'm going to mark as Mumper 12, U.S. patent 5,047,247.
(Mumper Exhibit 12, U.S. patent 5,047,247, marked for identification.)

BY MS. CHOW:
Q. Is this familiar to you?
A. I recall this in a general way.
Q. Is USP 5,047,247 an effervescent tablet?
MR. MUKERJEE: Objection. And Dr. Mumper, take as much time as you need to familiarize yourself with the document.
BY MS. CHOW:
Q. Or while you're skimming it, you can look and see whether or not it teaches the use of organic acids.
A. That's a second question because I can answer that one.
Q. All right, answer that. Go ahead.
A. Column 3, line 29 and 30, preferably citric acid is used as the organic acid.
Q. So this is a piece of prior art that the patentee distinguished over during prosecution, okay? So just so we're clear, USP '247 does teach the use of organic acids, right?
MR. MUKERJEE: Objection. Again, take as much time as you need.
THE WITNESS: '247 does utilize in

examples and in the specifications organic acids like citric acid.
BY MS. CHOW:
Q. In rendering your opinions, did you study whether or not USP '247 -- strike that.
In preparing your expert report, did you assess whether or not the '247 patent disclosed effervescent excipients?
A. Can you repeat that? I want to make sure I heard that correctly.
(Record read.)
THE WITNESS: Yes, in reviewing -- in preparing for my declaration, I considered whether patents in the prosecuting history, including '247, contained effervescent excipients.
BY MS. CHOW:
Q. And does the '247 patent teach the use of effervescent excipients?
MR. MUKERJEE: Objection.
THE WITNESS: In my opinion, '247 does teach the use of an effervescent excipient or excipient that is known to be an effervescent excipient in their tablet.

BY MS. CHOW:
Q. Does the '247 patent teach the use of an effervescent acid/base couple?
A. To the best of my knowledge, the '247 does not mention the word effervescent. It does have excipients in the tablet that are known to be effervescent excipients.
THE WITNESS: Can I ask to take a five-minute break? Is that okay, just a bio break? I wanted to ask before you ask another question.
MS. CHOW: That's okay.
(Recess taken from 2:06 p.m. to 2:08 p.m.)
BY MS. CHOW:
Q. Keep the '632 in front of you.
A. Okay.
Q. That's Mumper 9.
What is gastroresistance?
A. Are you asking for my interpretation of the '632 patent?
Q. No. I'm just asking you what is your understanding of what gastroresistance is.
A. My understanding of gastroresistance in

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a general way is, and as it relates to dosage forms, is the ability of the dosage form to protect to some measurable amount an incorporated drug substance from the enzymes and low pH that would otherwise harm either chemically or physically that drug substance.

Q. Does the '632 patent teach gastroresistance?

MR. MUKERJEE: Objection as to form.

BY MS. CHOW:

Q. If you want, I can direct you to some passages.

A. I can answer.

Q. Okay.

A. The '632 patent in column 3, lines 41 through 51 is talking about and teaching a tablet according to this invention that permits or impairs, imparts gastroresistance, and they are referring to the drug.

Q. Does the patent associate gastroresistance with the coating of -- strike that.

Does the patent associate gastroresistance with an enteric coat?

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MR. MUKERJEE: Objection.

THE WITNESS: In my opinion, '632 utilizes the well-known principle of enteric coating as to impart gastroresistance or to protect an acid sensitive drug from the gastric or stomach environment.

BY MS. CHOW:

Q. And when you say the enteric coat imparts gastroresistance or to protect an acid sensitive drug from the gastric or stomach environment, are you referring to the low pH of the stomach?

A. As I mentioned earlier, gastroresistance refers to -- the word "gastro" refers to the stomach which is known to have high concentration of enzymes and low pH.

Q. So for the '632 patent, the enteric coat helps protect the active ingredient from the low pH of the stomach, correct?

A. Yes.

Q. Is it fair to say the greater the gastroresistance, the lesser the influence of the low pH of the stomach?

A. Can you repeat that question? Or --

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okay.

Q. Is it fair to say the greater the gastroresistance, the lesser the influence of the low pH of the stomach?

A. Can you clarify that question? The lesser the influence of the pH of the stomach on what?

Q. Oh, I see. Okay.

I'm just trying to get the correlation between gastroresistance and pH. But is it fair to say the greater the gastroresistance, the lesser the influence of the low pH of the stomach on the active ingredient?

A. I would say that if you had granules, multiparticulate granules that are coated with an enteric coating and you could measure acid-resistance, let's say by doing an acid-resistance test, that you would expect a granule that had, let's say, more of a coating or a sufficient coating and you showed that it was more resistant, that the drug was more stable in those granules, a drug that was acid sensitive, that that would correlate, or the converse of that is if you had a granule that had an instance

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sufficient or incomplete coating and you measured more instability due to the low pH of the stomach, so I think that's consistent and I think that's a fair conclusion.

Q. Does gastroresistance means that there is reduced pH influence in the digestive track?

MR. MUKERJEE: Objection.

THE WITNESS: No. I think in the example that I just gave in answer to my last question is that you have a measurable cause and effect. And I think what's missing in your question is being able to measure and correlate the two.

BY MS. CHOW:

Q. So how would you phrase it, if basically the flaw is in my question?

A. I think you're getting at the claim construction and how I concluded that that claim was indefinite, that term was indefinite, and my conclusion is largely based on that you need to be able to measure where you're starting from and where you're going, and so just to have a general statement that they are correlated I think is indefinite.

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BY MS. CHOW:
Q. Okay. Let's isolate the term. Let's just talk about orally disintegrable so you'll be more comfortable with the question.
Let's say I have a tablet that disintegrates only in water but not in the mouth. Is that an orally disintegrable tablet?
A. I hear your question and you're asking me a tablet that will only disintegrate in water? Okay. So you have a glass of water. The tablet will only disintegrate in water. That was your words. So that means literally it cannot disintegrate in saliva, only in water, so an orally disintegrable tablet means one that is capable of disintegrating in water or in saliva. So based on the way you asked me that question, I would say no, because you said it only disintegrates in water, which means it's not capable of disintegrating in saliva so it doesn't meet that claim definition.
Q. Isn't your definition really that orally disintegrable tablet means a tablet that disintegrates in both water and saliva?
MR. MUKERJEE: Objection.

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BY MS. CHOW:
Q. You used the word "or" in our conversation but I'm getting the sense it might be "and" so can you just clarify for me?
MR. MUKERJEE: Objection, mischaracterizes the witness's testimony.
THE WITNESS: My position about the term disintegrable tablet is consistent in my opinion with what '994 teaches about an orally disintegrable tablet, that it can be disintegrated in the mouth with very little water and in the presence of saliva or it may be administered dissolved or disintegrated with water. My definition of disintegrable tablet is in my opinion completely in agreement with what '994 teaches.
BY MS. CHOW:
Q. I'm just trying to understand kind of the boundaries of your claim construction, and it seems to me that you're saying, but you can correct me if I'm wrong, that an orally disintegrable tablet does not include a tablet that can only be disintegrated in water, right?
THE WITNESS: Can you read the question

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back to me?
(Record read.)
THE WITNESS: Maybe the way the question is phrased I'm having problems with.
Again, my position in terms of claim construction on what an orally disintegrable tablet is is completely consistent with column 17, line '61 through '66, where it says that it may be dissolved or disintegrated with water and with saliva.
So in response to your question, this tablet can -- is capable of disintegrating in the oral cavity and per the teaching of '994, the tablet may also be administered, dissolved or disintegrated with water. So '994, again what I am concluding is that they are teaching a tablet that can do either, not one or the other, but either and that's my position and it's consistent with the teaching of '994.
BY MS. CHOW:
Q. I guess it seems to me there's a distinction between two concepts. One concept is what makes an orally disintegrable tablet an orally disintegrable tablet, and there's a second

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concept which is how that tablet can be administered. Do you understand what I'm trying to say? I'm trying to understand in terms of your fundamental definition for orally disintegrable tablet. If there's a distinction between what in essence makes an orally disintegrable tablet an orally disintegrable tablet versus the fact that there may or may not be various methods of administering that orally disintegrable tablet. That's what I'm trying to understand.
It's hard to ask these questions, hard for you to answer but that's the root of my questioning, okay?
A. And I was asked to opine about the definitions of terms in the '994 patent. And one of those terms that I very carefully considered is the term disintegrable and what that means. And again, that is an adjective that means it's capable of disintegrating.
And when the '994 patent was applied for, mid to late '90s, ODTs, orally disintegrating tablet, that's a verb, that it must be a disintegrating tablet. The inventors chose a word that has a literal English meaning and that is an

adjective meaning that it's capable with, and I, in my opinion, the inventors were very careful in using the word disintegrable instead of disintegrating, and the reason I think in my opinion that they use the word disintegrable meaning capable of is they were explicitly teaching different administration methods and envisioned that their tablet that was capable of disintegrating could be administered either directly in the mouth or added to a tablet for dissolution and disintegration and then that would be swallowed.

Q. So if a tablet disintegrates in water outside of the mouth and then is swallowed by the patient, that falls under your construction of orally disintegrable tablet, yes?

A. You're asking that question in a very general way. I was asked to opine about '994 and what the term orally disintegrable tablet means. With respect to '994, if that tablet was placed in water and then swallowed, consistent with the teaching of '994 and their claim, I would agree that's an orally disintegrable tablet.

Q. So now let me push it a little bit

further.

If a tablet disintegrates in water outside of the mouth and then is swallowed by the patient but that same tablet cannot disintegrate inside the mouth, okay, does that tablet fall under your construction of orally disintegrable tablet as set forth in the '994?

A. That now falls outside as required by the '994 patent that when they talk about the tablet, they mean a specific tablet that has the properties of being able to -- it's capable of dissolving or disintegrating with little water and in the presence of saliva in the cavity, and it says also the tablet. The same tablet may be administered dissolved or disintegrated with water.

So my answer when you asked the question so if you have a tablet that is dissolved in water and swallowed but that same tablet cannot disintegrate in the mouth, that falls outside.

Q. So do you agree that it is a defining characteristic of an orally disintegrable tablet that it must be able to disintegrate inside the mouth?

A. So you're -- just so I understand you, it must disintegrate in the mouth, the claim -- my position is that it must be capable of, that an orally disintegrating tablet could be applied -- I'm sorry, an orally disintegrable tablet may be dosed by other routes of administration but it must be capable. You asked the question it has to.

Q. So is it a defining characteristic of an orally disintegrable tablet that it must be capable of disintegrating inside the mouth?

A. Per '994 teaching, specifically claim 1, an orally disintegrable tablet is a tablet capable of disintegrating in the mouth. It doesn't explicitly have to but it has to be capable of.

Q. For the '632, does your construction for orally disintegrable as set forth -- sorry, strike that.

Does your construction for disintegrable for the '994 patent apply equally to the term disintegratable for the '632 patent?

MR. MUKERJEE: Objection, asked and answered.

THE WITNESS: In looking at '632, claim 1, a rapidly disintegratable tablet, as I have said, that means that it's capable of disintegrating. It's intended for oral administration and it specifies disintegration in the buccal cavity. So it's basically as I -- in my opinion, what claim 1 is doing in the first sentence is saying that you have a rapidly -- you have a tablet that's capable of disintegrating for oral administration, and it specifies it must disintegrate in the buccal cavity.

So what's different in '632, and I think this is completely in line with my position, is that it's specifying exactly where the tablet must disintegrate. And it's going a step further than just saying it's capable. Now it's saying it has to disintegrate in the buccal cavity. So where the '994 patent said it's capable of disintegrating in these different places, claim 1 of the '632 is now being literally very specific. A tablet that's capable of disintegrating must be given orally and

ordinary skill in the art of the '994 and '632 should have more education and more work experience than what was set forth in the omeprazole court decision?

MR. MUKERJEE: Objection.

THE WITNESS: That's not exactly what I'm saying. I didn't say more education. Just to be clear, I'm saying that the person must have a higher degree. You could have possibly someone with 10 undergraduate degrees. That's a lot of education, perhaps more time than one Ph.D.

What I am saying is that Dr. Byrn's definition of someone with ordinary skill I believe is incorrect in my experience and his support for that definition of somebody with ordinary skill is flawed.

BY MS. CHOW:

Q. Prior to this litigation, were you familiar with Dr. Byrn? Had you heard his name before, see his publications?

A. Yes, I know Dr. Byrn.

Q. Do you have any understanding as to his reputation?

A. Yes, I have my personal -- I have a personal view on his reputation. I don't know how others view his reputation.

Q. And what is your personal view?

A. Thank you.

Q. How could I not follow up on that answer?

A. I've known Dr. Byrn for 20, 25 years. Faculty at Purdue. I've listened to his lectures before. He came down to the University of Kentucky and gave a lecture. He was an expert witness on the Watson Cephalon case on the third patent, the one that I was not an expert witness on.

My opinion of Dr. Byrn is that he is an expert in -- and I highly regard him in the area of solid state chemistry, crystalline habits of drugs and powders, polymorphism, so aspects related to solid state stability and characterization of those materials, and his CV lists 160 publications. I'm just estimating that 90 percent, 95 percent deal with what I just described and so he's highly regarded in that area.

I do not know him to be a person with the reputation in ODTs. He -- his curriculum vitae does not document work with ODTs. I understand that he claims to have submitted proposals on ODTs and that in his laboratory or laboratories, he's working on ODTs. That is not indicated, at least to me, on his curriculum vitae.

Q. What is your area of expertise?

A. My area of expertise is in the area of drug delivery, advanced drug delivery systems. I have pursued various types of delivery systems, almost every route of administration, for 20 or 25 years. I teach a course on dosage forms. I taught it for 13 years to pharmacy students and we talked about ODTs and sustained-release oral systems, and as I told you earlier, I was a expert witness representing Watson in the Fentora case, which is an ODT.

Q. Does your CV detail any work that you have done on ODTs?

A. I do not think that my CV has the term ODT.

Q. That doesn't answer my question.

Does your CV describe any prior work by you on ODTs?

A. I think I did answer the question. It doesn't -- it doesn't mention the term orally disintegrating tablet.

MS. CHOW: Okay. Let's take a break. I just want to make sure I don't have any follow-up questions.

(Recess taken from 4:00 p.m. to 4:14 p.m.)

MS. CHOW: I have no further questions for you.

MR. MUKERJEE: Mylan has no questions.

(Time noted: 4:14 p.m.)

_____

DR. RUSSELL MUMPER

Subscribed and sworn to before me this _____ day of _____, 2012.

_____

Notary Public